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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,815	12/07/2000	Akira Aomatsu	5836-01-MJA	5030

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,815	AOMATSU, AKIRA	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28 and 31-38* is/are pending in the application.

4a) Of the above claim(s) *32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28,31 and 33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _.

DETAILED ACTION

Status of Application

1. By Amendment filed November 21, 2005, claim 25 has been amended; claims 29 and 30 have been cancelled; and claims 34-38 have been newly added. Claims 25-28, 31 and 33-38 are currently pending for prosecution on the merits.

2. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114.

Summary of Action

3. The objection of the claim 25 is not maintained in light of the amendment.

4. The objection of the amendment filed May 27, 2005 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure is not maintained in light of the amendment.

5. The rejection of the claims 25-31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is not maintained in light of the amendment.

6. The rejection of the claims 25-27 and 31 under 35 USC 102(b) rejection as being anticipated by Woodruff is maintained for the reasons of the record.

7. The rejection of the claims 25-28, 31 and 33 under the judicially created doctrine of double patenting over claims 28, 35-37 of Copending US Application No. 09/674,819 is maintained for the reason of record.

8. Claims 25-28, 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao (US 5660861) in view of Robson et al. (US 4126684), and further in view of Costa et al. (US 5248678).

9. Applicant's amendment necessitates a new ground of rejection in this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 25-27, 29 and 31 are rejected under 35 USC 102(b) as being anticipated by Woodruff (US 5084479).

Woodruff discloses a solution comprising N-methyl-D-aspartic acid and gabapentin with presence of TTX (column 8, lines 4-14).

Since the interpretation of the instant claims allows for the inclusion of any other unspecified ingredients even in major amounts in said composition, the referenced final solution containing N-methyl-D-aspratic acid, gabapentin and water, with the presence of TTX, anticipates the claimed invention.

Although the reference is silent about "wherein as compared with a second composition that contains the same components as the pharmaceutical composition...in the second composition", such preamble to the claims gives no patentable weight to the claimed invention since the product is not dependent upon the manner in which is compared. Thus, Woodruff anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 25-28, 31 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao et al. (US 5660861) in view of Robson et al. (US 4126684), and further in view of Costa et al. (US 5248678) and Bays et al. (WO 96/11680).

With claims 34-38,

Jao discloses a dosage form for delivering an antiepileptic drug (i.e., 4-amino-3-substituted butanoic acid derivative such as gabapentin) and the method of making the dosage form (col. 6, lines 52-67; col. 17, line 23 thru col. 18, line 27; abstract; col. 1, lines 9-17; col. 3, line 66 thru col. 4, line 5; col. 10, line 65 thru col. 13, line 44), for example a tablet or capsule (col. 5, lines 14-26; col. 15, lines 34-53; fig. 1), wherein said active ingredient is formulated with secondary ingredients such as sorbitol (col. 7, lines 42-52), and hydroxypropylcelllose (col. 9, lines 8-25; col. 17, lines 23-52). The method comprises mixing the drug with the composition forming ingredients (col. 12, line 63 thru col. 13, line 24).

Robson discloses a composition comprising 4-amino-3-substituted butanoic acid derivative such as baclofen, alpha amino acid such as glycine, auxiliary agent (i.e., sorbitol, mannitol, lactose, etc...) and aqueous gelatin solution. See Example 2.

Costa is being supplied as the reference to demonstrate the art recognized functional equivalent of gabapentin and baclofen as GABA agonists.

The teaching of Jao differs from the claimed invention (i) in the inclusion of a neutral amino acid such as glycine in a composition and (ii) the specific amount of alpha-amino acid (e.g., glycine) in said composition. To incorporate such teaching into the teaching of Jao, would have been obvious in view of Robson who teaches the use of glycine in 4-amino-3-substituted butanoic acid derivative (i.e., baclofen) and Costa who teaches the use of gabapentin as functional equivalent of baclofen as a GABA agonist.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to include a neutral amino acid such as glycine as taught by Robson et al. in composition of Jao. One of ordinary skill in the art would have been motivated to include a neutral amino acid such as glycine in the composition of Jao for the advantage of providing a delivery system that would delivery the drug formulation in continuous-release dose for predictable and improve therapy (Jao: col. 3, lines 20-25) since both Jao and Robson disclose a pharmaceutical excipient such as sorbitol and a drug that is 4-amino-3-substituted butanoic acid derivative (Jao: col. 6, lines 52-67, and col.7, lines 42-52; Robson: col. 2, lines 5-8, and col. 3, lines 54-59). Furthermore, since the equivalence of gabapentin and baclofen as GABA agonist is well known in the art, the selection of any of known GABA agonists from limited examples of Costa to arrive at the claimed invention would be within the level of ordinary skill in the art.

In addition, optimization of amounts of known active and/or inactive ingredients in a composition or determination of the specific delivery dosage form having optimum therapeutic index is well considered within the skill of the artisan, absent evidence to the contrary.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

12. Claims 25-28, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jao et al. (US 5660861) in view of Robson et al. (US 4126684), and further in view of Costa et al. (US 5248678) and Bays et al. (WO 96/11680).

The modified teaching of Jao includes all that is recited in claims 25-28, 31 and 33 except the preparation of said composition in liquid formulation.

Bays is being supplied as the reference to demonstrate the routine knowledge in preparing 4-amino-3-substitued butanoic acid derivative (i.e., gabapentin) in various dosage forms including solid or liquid dosage form (page 1, lines 24-34; page 3, line 24 thru page 5, line 17).

However, those of ordinary skill in the art would have been readily optimized effective dosages forms including liquid dosage forms as determined by good medical practice and the clinical condition of the individual patient. One having ordinary skilled in the art would have

been motivated to make such modification to extend the usage of said composition in liquid dosage forms to accommodate patient's preference and needs where the compliance could be improved with effective and well tolerated drug.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 25-28, 31 and 33-38 are rejected under the judicially created doctrine of double patenting over claims 28-39 of Copending US Application No. 09/674,819.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claimed composition is overlapping with the claimed scope of the copending application. Since the interpretation of the instant claim allows for the inclusion

of any other unspecified ingredients even in major amounts in said composition, the presence of humectant in said composition in the copending application makes obvious the instant claims.

With respect to the determination of concurrent dosage forms, particularly liquid form, those of ordinary skill in the art would have been readily optimized effective dosages forms including liquid dosage forms as determined by good medical practice and the clinical condition of the individual patient. One having ordinary skilled in the art would have been motivated to make such modification to extend the usage of said composition in liquid dosage forms to accommodate patient's preference and needs where the compliance could be improved with effective and well tolerated drug.

Conclusion

14. No Claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon